



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------------|------------------------|
| 10/527,538 | 03/11/2005 | Chester Sutterlin | 072US1 | 8929 |
| 7590 | | 08/21/2007 | | |
| Nuvasive Portfolio IP P O Box 52050 Minneapolis, MN 55402 | | | EXAMINER CUMBERLEDGE, JERRY L | |
| | | | ART UNIT 3733 | PAPER NUMBER |
| | | | MAIL DATE 08/21/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,538

Applicant(s)

SUTTERLIN ET AL.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58, 59, 62-65 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen (US Pat. 5,733,288).

Allen discloses a method for removing intervertebral disc material, comprising the steps of: creating a working channel from a patient's skin to an intervertebral disc space [since the device can be used on bone, column 1, lines 55-63, and specifically within the spine in order to correct spinal problems, column 1, lines 10-15, in order to remove fibrous soft tissue (e.g. a spinal disc) and since to remove this tissue the device must necessarily first reach the tissue (e.g. the spinal disc) through a channel, which would lead to the intervertebral disc space, where the disc being removed resides], inserting a brush member into said intervertebral disc space (since to remove the fibrous tissue, e.g. the spinal disc, the brush member must be placed within the disc space, where the disc resides), said brush member having a plurality of bristle members (Fig. 2, near ref. 10) defining a capacity for carrying intervertebral disc material (Fig. 10, since disc material can be received within the spaces between the bristles)(column 3, lines 16-19); manipulating said brush member within said intervertebral disc space to receive intervertebral disc material within said brush member (column 5, lines 1-4); and

Art Unit: 3733

removing said brush member from said intervertebral disc space (Fig. 2, since the device is clearly designed to be removed from the body when the surgery is completed). The step of creating a working channel to the intervertebral disc space is accomplished via at least one of percutaneous surgical procedure and an open surgical procedure (since the device, at the very least, in order to reach the bone and soft tissue, column 3, lines 15-19, the device must pass through the skin). The brush member includes a stem member (Fig. 2, ref. 20), and further includes the step of providing a drive assembly (column 5, lines 1-6, i.e. the rotary hand piece) capable of engaging with said stem member for manipulating said brush member within said intervertebral disc space (column 5, lines 1-6). The drive assembly comprises one of a powered drive assembly coupled to said stem member and a manual drive assembly coupled to said stem member (column 5, lines 1-6, i.e. the rotary hand piece). The powered drive assembly is a power drill (column 2, lines 59-62). The manual drive assembly includes a handle member capable of being coupled to said stem member (Figs. 5-7, column 5, lines 1-6, i.e. the rotary hand piece must comprise a stationary portion to grip, or the device would spin from the surgeons hands when used). The drive assembly includes a stop member (Fig. 5, lip to the right of the brush member) coupled to said stem member for controlling the depth to which said brush member can be advanced into said intervertebral disc space.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60, 61, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Pat. 5,733,288) in view of Ouchi (US Pat. 5,899,850).

Allen discloses the claimed method except for the step of inserting a brush member includes, prior to said step of inserting said brush member, positioning a protector near an entrance into said intervertebral disc space for establishing a barrier between said brush member and at least one of neural tissue, dura tissue, and vasculature adjacent to said entrance. The protector comprises a cannula dimensioned to extend to said entrance of said intervertebral disc space, said cannula having an inner lumen dimensioned to slideably receive said brush member for passage into said intervertebral disc space. The cannula includes a lip member at a distal end thereof dimensioned to retract at least one of said neural tissue, dura tissue, and vasculature adjacent to said spine. The inner lumen of said cannula and said brush member have approximately the same cross-sectional shape.

Ouchi discloses a method of inserting a brush member (Fig. 16, ref. 2) into tissue (column 1, lines 5-10), wherein prior to said step of inserting said brush member, positioning a protector (Fig. 16, ref. 6) which establishes a barrier between said brush member and other tissue, since the protector surrounds the brush (Fig. 16). The protector comprises a cannula (Fig. 16, ref. 6) dimensioned to extend to said entrance

Art Unit: 3733

of said intervertebral disc space, said cannula having an inner lumen (Fig. 16, near ref. 14A) dimensioned to slideably receive said brush member for passage into said intervertebral disc space (Fig. 16 and Figs. 1, 2A, 2B). The cannula includes a lip member (Fig. 4, e.g. ref. 5) at a distal end thereof dimensioned to retract at least one of said neural tissue, dura tissue, and vasculature adjacent to said spine (Fig. 4), since as it expands it can retract tissue. The inner lumen of said cannula and said brush member have approximately the same cross-sectional shape (Fig. 16). This tube is useful in allowing the brush to be used for cytology purposes and prevents the cells collected from being knocked off of the brush (column 1, lines 10-30).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Allen with the steps of using a protector as taught by Ouchi in order to allow the brush of Allen to be used for cytology and puposes and prevent the cells collected from being knocked off of the brush (column 1, lines 10-30).

Claims 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Pat. 5,733,288) in view of Ouchi (US Pat. 5,899,850) in view of Ouchi (US Pat. 6,210,377 B1).

Allen in view of Ouchi (US Pat. 5,899,850) disclose the claimed invention except for the protector comprising a retractor having at least one blade member for establishing a barrier between said brush member and said body tissue adjacent to said entrance. The body tissue adjacent to said entrance includes at least one of neural

Art Unit: 3733

tissue and dura tissue of the spine, and wherein said retractor includes a first blade member for retracting said neural tissue and a second blade member for retracting said dura tissue. The first blade member and second blade member have a fixed angle therebetween. The first blade member and second blade member have a variable angle therebetween. The retractor includes a handle assembly for varying said angle between said first blade member and said second blade member.

Ouchi (US Pat. 6,210,377 B1) discloses placing a blade on the end of a retractor (column 21, lines 13-16), in order to assist in proper insertion of other devices through the retractor (column 21, lines 7-12).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the retractor of Ouchi (US Pat. 5,899,850) with the blade of Ouchi (US Pat. 6,210,377 B1), in order to assist in proper insertion of other devices through the retractor (column 21, lines 7-12). By constructing the device in this manner, the retractor of Ouchi (US Pat. 5,899,850) would then be provided with two bladed members (e.g. a first blade member and a second blade member), since the end of the retractor of Ouchi (US Pat. 5,899,850) is split in two different sections (Fig. 2B, ref. 14A). The two sections would be capable of remaining stationary to each other, or moving relative to each other (column 8, lines 47-54).

Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Pat. 5,733,288) in view of Worthen et al. (US Pat. 5,445,164).

Art Unit: 3733

Allen discloses the claimed invention except for the manual drive assembly including an extension member coupled to said handle and a quick-connect coupling assembly for releasable connection to said stem member.

Worthen et al. discloses a quick-connect assembly coupled to a handle (column 1, lines 37-39), which is used to quickly detach components from each other (column 1, lines 37-39).

It would have been obvious to have constructed the device of Allen with a quick-connect assembly as taught by Worthen et al., in order to allow one to quickly detach the components from each other (column 1, lines 37-39).

Response to Arguments

Applicant's arguments with respect to claims 58-74 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). Furthermore, it is noted by the Examiner that although Applicant states that the claims are being "reintroduced", they have also been amended to add terms that more narrowly define the invention (e.g. "intervertebral disc", "intervertebral disc space").

Art Unit: 3733

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



NICHOLAS D. LUCCHESI
SUPERVISING PATENT EXAMINER
TECHNICAL CENTER 3700